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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/074,715
Filing Date: February 13, 2002
Appellant(s): MAGGIORE ET AL.

Talivaldis Cepuritis
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed March 22, 2006 appealing from the Office action mailed September 22, 2005.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| 6,579,688 | STEAFFENS et al. | 6-2003 |
| 5,616,460 | FIGARD | 4-1977 |

**(9) Grounds of Rejection**

The following grounds of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-18, 20-22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steaffens et al. (US Patent 6,579,688) in view of Figard (US Patent 5,616,460).

Steaffens et al. disclose a biological fluid preserving composition suitable for lysing and preserving (stabilizing) biological fluids having polypeptides and antigens (see Abstract and column 3, lines 55-64). Steaffens et al. provide that the composition has a chelating agent, which is ethylenediaminetetraacetic acid (EDTA). Steaffens et al. also provide that the composition has a cell lysing agent (dispersing), which is ethanol. See column 4, lines 33-38, 45-53, and line 66 to column 5, line 1. See also column 6, lines 1-62. The composition also includes a preservative such as butylated hydroxy anisole (BHA). In column 2, lines 8-21, it is exemplified that sodium azide is used in prior art as a preservative for preserving compositions. In column 2, lines 36-40, it is exemplified that ethylene glycol is used in prior art as antifreeze agent for preserving compositions. Steaffens et al. further teach chelating agent concentrations of 0.05 to about 0.5 weight percent (0.01mM to 100mM), cell lysing agent concentrations of 5 to about 25 percent (0.1% to 30% w/v), and preservative concentrations of up to about 0.1 weight percent (0.01% to 10% w/v) (see especially column 6, lines 12-53).

Steaffens et al. has been discussed supra. Steaffens et al. differ from the instant invention in failing to disclose antifreeze at a concentration of up to about 50 weight

percent of antifreeze agent. Steaffens et al. also fail to teach incorporating the preserving composition into a kit format (packaged form).

Figard discloses a reagent composition having preserving capabilities which includes antifreeze which is ethylene glycol, an organic $C_1$-$C_{10}$ polyol, used for its superior ability to preserve binding capacity of antibodies to antigens in biological fluids. Figard teaches use of ethylene glycol at concentrations of up to 50 weight percent (4% to about 8% weight per unit volume) (see column 2, lines 53-67). Figard teaches the preserving composition as including sodium azide as preservative. Figard also teaches incorporating the reagent into a kit format (reagent packaged form) (see column 6, line 62 to column 7, line 2)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate ethylene glycol as taught by Figard into the preserving composition taught by Steaffens, because Figard found that ethylene glycol used in such concentrations provide superior preserving capacity in binding interactions between polypeptides. It would also have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the preserving composition as taught by Steaffens, into a kit arrangement as taught by Figard because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

**(10) Response to Argument**

A) Applicant argues that not all claim limitations have been taught or suggested by the prior art and that not all words in the claims have been considered in judging the patentability of the claims against the prior art. Applicant argues that the Steaffens et al. focuses on preserving compositions containing a serum protein and a detergent as active ingredients, and that Steaffens et al. only provide a generic list of components that could be present in the stabilizing compositions. Additionally, Applicant contends that the specific teaching of Steaffens et al. is that serum protein (fetal calf serum and bovine serum albumin) and detergent are "required" and important as active ingredients to achieve suitable preservation of antigens and polypeptides. Applicant also argues that the presence of a serum protein in Steaffens et al. raises potential storage stability issues for compositions, since they can potentially degrade and support microbial growth.

In response, independent claim 12 recites the transition language "consisting essentially of" and lists a chelating agent in weight percent concentration and a cell lysing agent in weight percent concentration. The list further includes, a preservative which does not appear to be required in reciting, "[0] up to about 0.1 weight percent" concentration but includes "up to about 0.1 weight percent", and an antifreeze which does not appear to be required in reciting, "[0] up to about 50 weight percent" concentration but includes "up to about 50%". Claim 12, hence, is recited so broadly as to invite a generic list of components that could be present in the biological preserving composition, any list of chelating agents, any list of lysing agents, any list of

preservatives, which depending on their types, may provide different effects upon the preserving capability of the claimed composition.

Specifically and contradictory to Applicant's argument, the detergents as taught by Steaffens well encompass the recited "lysing agents" in claim 12. Claim 12 has, therefore, been determined to read on the teachings of Steaffens et al. because Applicant has failed to provide how the claimed composition is distinct and rendered suitable for lysing and preserving blood samples for thyroid stimulating hormone analysis for a period of at least three weeks at ambient temperatures, over the consonant chelating agents, lysing agents (or detergents), preservatives, and concentrations thereof, taught by Steaffens et al. Moreover, Applicant's argument against Steaffens et al. reference is not on point, as it only argued the Steaffens et al. reference as to its requirement of serum protein and detergent as active ingredients in the prior art preserving composition; however, Applicant has not provided information to assess how the serum proteins and detergents in Steaffens et al. would have materially affected the claimed composition, or what aspect of the prior art serum proteins and detergents would have affected the novel characteristic of the claimed inventive composition, so as to establish distinction and novelty of the claims over the prior art.

In response to Applicant's argument that the presence of serum proteins in Steaffens et al. raises potential storage stability issues for compositions, since they can potentially degrade and support microbial growth, it is noted that the claimed invention includes therein a list of antimicrobial preservatives consonant to those taught by Steaffens et al. Accordingly, Applicant has not provided information to assess how the

serum proteins in Steaffens et al. would have materially affected the claimed composition, or what aspect of the prior art serum proteins would have differentially affected the novel characteristic of the claimed inventive composition, so as to be distinct from the prior art composition, so as to establish novelty of the claims over the prior art.

B) Applicant argues that Figard teaches an entirely different type of composition than Steaffens et al., containing dithiothreitol (DTT) and ethylene glycol as active buffering components; hence, the combination of Steaffens et al. with Frigard does not render obvious the claimed invention.

In response, claim 12 does not require antifreeze in reciting, "[0] up to 50 weight percent". Specifically and contradictory to Applicant's argument, ethylene glycol as taught by Figard well encompasses the recited "antifreeze" in claim 12. Alternatively, Applicant's argument against the combined teaching of Steaffens et al. and Figard is not on point, as it only argued the Figard reference as to its requirement of DTT and ethylene glycol as active ingredients in the prior art composition; however, Applicant has not provided information to assess how the DTT and ethylene glycol in Figard would have materially affected the claimed composition, or what aspect of the prior art would have affected the novel characteristic of the claimed inventive composition, so as to establish distinction and novelty of the claims over the combined prior art.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Gailene R. Gabel

5/2/06

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